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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| EXAMINER | |
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| ART UNIT | PAPER NUMBER |
| | 14 15 |

**DATE MAILED:**

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

| Office Action Summary | Application No. 09/065,902 | Applicant(s) TANZI ET AL. | |
|---|---|---|---|
| | Examiner Karen Clemens | Art Unit 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

**Status**

1)☒ Responsive to communication(s) filed on *31 July 2000* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *2-10 and 12* is/are pending in the application.

4a) Of the above claim(s) *6-8 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-5,9 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

**Attachment(s)**

5)☐ Notice of References Cited (PTO-892)
6)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
7)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other:

***DETAILED ACTION***

**1.** Applicant's amendment filed 7/31/00 (Paper No. 12), is acknowledged.

**2.** Claim 11 has been cancelled.
Claims 2-10 and 12 are pending.

Claims 6-8 and 12 stand withdrawn from further consideration by the Examiner as being drawn to a nonelected invention (see 37 C.F.R. 1.142(b)). The Election was made without traverse in Paper No. 9, filed 1/18/00.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

**3.** Formal drawings have been submitted which fail to comply with 37 CFR 1.84 as noted in form PTO-948, filed 3/30/00, with Paper No. 10. Applicant submit they will provide formal drawings when allowable subject matter is indicated.

**4.** Receipt is acknowledged of the executed copy of the corrected Declaration wherein the serial number for the provisional application to which priority is claimed is corrected from 06/044262 to 60/044262.

**5.** Receipt is acknowledged of the Computer Readable Form of the Sequence Listing for the instant application and is now in sequence compliance in accordance with 37 C.F.R. 1.821 through 1.825.

**6.** In view of the amendment filed 7/31/00 (Paper No. 12), the following rejections remain:

The following is a quotation of the appropriate paragraph of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 2-3 stand rejected under 35 U.S.C. 102(a) as being anticipated by Vito et al. (*J. Biol. Chem.* 271(49):31025-31028, 1996) for the same reasons set forth in Paper No. 10.

Applicant's arguments, filed 7/31/00 (Paper No. 12), have been fully considered but are not found persuasive.

Applicant argues that the antibody taught by Vito et al. (Vito et al. teach a polyclonal antibody raised against a murine PS2 CTF peptide spanning amino acids Met $^{438}$-Ile $^{448}$ (full length = 448 amino acids) which are identical in both mouse and human PS2) binds to *any* PS2 polypeptide having the amino acids to which the antibody was made, such as full-length PS2, normal 25KDa PS2 CTF, 20 KDa PS2 CTF and ALG-3 while the instant antibody is specific only to the 20 kDa PS2 CTF.

However, as noted in the specification in Figure 7, panel c (described on page 10, line 10 to page 11, line 3) and Figure 8 (described on page 11, lines 4-10) the instant αPS2Loop antibody used to detect the 20 kDa PS2-CTF was also able to bind to the full-length form of PS2 (54kDa) as well as the normal PS2-CTF cleavage product of 26 kDa. The presence of the different forms of PS2 in the αPS2Loop immunoblots appears to differ based on the source of the sample (e.g. detergent resistant fraction is enriched in the 20 kDa PS2-CTF fragment) rather than its specificity to the 20 kDa PS2-CTF.

Therefore, the reference teachings anticipate the claimed invention.

**7.** The following is a quotation of 35 U.S.C.103 which forms the basis for all obviousness rejections set forth in this Office action:

> "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

**a.** Claim 4 stands rejected under 35 U.S.C.103(a) as being unpatentable over Vito et al. (*J. Biol. Chem.* 271(49):31025-31028, 1996) in view of Dalbow et al. (US Patent #4116776, 1978) for the same reasons set forth in Paper No. 10.

**b.** Claim 5 stands rejected under 35 U.S.C.103(a) as being unpatentable over Vito et al. (*J. Biol. Chem.* 271(49):31025-31028, 1996) in view of Janeway et al. (*Immunobiology*, New York, Current Biology, 1997) for the same reasons set forth in Paper No. 10.

Applicant's argue that neither Dalbow et al. or Janeway et al. teach an antibody having specific binding affinity to the 20 kDa PS2 C-terminal fragment. Applicant's submit that if the 35 U.S.C.102(a) rejection of claims 2-3 using the Vito et al. reference was withdrawn that the Dalbow et al. and Janeway et al. references alone would be inadequate to sustain the 35 U.S.C.103(a) rejections of claims 4 and 5.

However, the Examiner has not withdrawn the 35 U.S.C.102(a) rejection of claims 2-3 using the Vito et al. reference, and therefore maintains the 35 U.S.C.103(a) rejections of claims 4 and 5 citing references Dalbow et al. and Janeway et al.

**c.** Claims 9-10 stand rejected under 35 U.S.C.103(a) as being unpatentable over Tanzi et al. (*Neurobiology of Disease* 3:159-168, 1996) in view of Miller et al. (*Ann. New York Acad. Sci.* 696:133-48, 1993) for the same reasons set forth in Paper No. 10.

Applicant's arguments, filed 7/31/00 (Paper No. 12), in conjunction with the Declaration of Co-Inventors under 37 C.F.R. § 1.132, have been fully considered but are not found convincing.

Applicant's position that the Declaration under 37 C.F.R. § 1.132 filed 7/31/00 by the inventors, which addresses the contribution of the authors on an abstract (Kim et al.) entitled "Proteolytic Processing of Wildtype and Mutant forms of Presenilin 2", in *Neurobiology of Aging*, 17:S155, July 1996, which is referenced in Tanzi et al., invalidates the Tanzi et al reference in the 35 U.S.C.103(a) rejection.

However, the Examiner notes that to invalidate a reference used in a 35 U.S.C.103(a) rejection by submitting a 37 C.F.R. § 1.132 Declaration to demonstrate the publication as the inventor's own work, the publication cited in the Declaration must be that used in the 35 U.S.C.103(a) rejection, i.e. the Tanzi et al. reference.

**8.** No claim is allowed.

**9. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**10.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Clemens whose telephone number is (703) 308-8365. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Karen Clemens, Ph.D.
Patent Examiner
Technology Center 1600
October 23, 2000

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